UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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SHAFIGHEH KOUBLANI,

Plaintiff,

-against-

2:20-cv-01741-DRH-AYS

COCHLEAR LIMITED and COCHLEAR AMERICAS,

Defendants.

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PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANT COCHLEAR AMERICAS CORPORATION'S MOTION TO DISMISS THE AMENDED COMPLAINT

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Plaintiff Shafigheh Koublani ("Plaintiff") submits this Memorandum of Law in Opposition to defendant Cochlear Americas Corporation's ("CAM") motion to dismiss the Amended Complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

I. STATEMENT OF RELEVANT FACTS

The strict product liability and negligence claims asserted in this action arise out of the failure of an MRI Kit (the "MRI Kit") which was designed, manufactured, distributed, sold and injected into the stream of commerce by defendants COCHLEAR LIMITED and COCHLEAR AMERICAS (collectively referred to as the "Defendants"), to permit recipients of defendants' separate, cochlear implant product to undergo magnetic resonance imaging ("MRI"), without first having the implant surgically removed.

Plaintiff, who has severe hearing deficits, had defendants' Cochlear Nucleus CI522 implant (the "Implant") surgically implanted on March 14, 2017. The Implant was designed and distributed by Defendants to provide a sense of sound to people who, like Plaintiff, are deaf or hearing impaired.

The Implant, itself, includes a magnet and other metal parts which were surgically implanted under the Plaintiff's skin. Therefore, Plaintiff was advised that she is unable to undergo MRI testing, unless the subcutaneous components of the Implant are first removed or she is outfitted at the MRI facility with an MRI Kit which Defendants sell separately.

On February 14, 2018, Plaintiff underwent an MRI procedure with the magnet and other metal component parts of the Implant *in situ*, under her skin, utilizing the MRI Kit which the MRI facility obtained in advance from Defendants. Unfortunately, during the MRI procedure, the MRI Kit

failed to function as intended and the magnet became painfully dislodged under Plaintiff's skin. As a result, the MRI was terminated and Plaintiff was required to undergo surgery to remove the dislodged Implant and to implant another.

As a result of the MRI Kit's failure, Plaintiff commenced a product liability claim against Defendants[1] seeking damages for the severe injuries she sustained and subsequent surgeries she endured to explant the Implant and re-implant another.

The claims asserted in this action involve only the failure of the MRI Kit. No claim is asserted in this action, nor is any claim anticipated to be asserted against the Implant itself. However, in defense of this action, Defendants conflate the two, separate products - the MRI Kit and the Implant – and argue that Plaintiff's claims are preempted by the Medical Device Amendment of 1976 ("MDA"), relying solely on the Food and Drug Administration's (the "FDA") pre-market approval ("PMA") and supplemental PMA ("Supplemental PMA") obtained for the Implant. As shown below, the PMA and Supplemental PMA approval granted to the Implant do not extend to the MRI Kit and, therefore, Plaintiff's claims against the MRI Kit are not preempted.

Dispositive, documentary evidence produced by Defendants and retrieved from the FDA proves the claims asserted in this action against the MRI Kit are not preempted by the MDA. In short, CAM cannot shield itself from liability arising from the MRI Kit's failure by relying upon FDA approval of the Implant, because the MRI Kit was never reviewed or approved by the FDA, and Defendants never sought such approval for the MRI Kit. Moreover, as explained below, although the Implant is a so-called "Class III device" under FDA regulations, for which FDA pre-market approval was required, the MRI Kit is a separate, distinctly categorized "Class II device" under FDA regulations, and was specifically exempted from the PMA process under the Food and

[1] Plaintiff originally commenced the instant action in New York State Supreme Court, Nassau County, where she resides.

Drug Administration Act of 1997. Because of its exemption from the PMA process, the MRI Kit was never examined or approved by the FDA and, therefore, the MRI Kit is not entitled to the immunity from State law claims afforded by the MDA to Class III devices that have been scrutinized and approved by the FDA.

Nevertheless, despite the two products' separate classifications and the unavailability of FDA pre-market approval for the Class II MRI Kit, – a distinction with fatal consequences for the arguments offered by Defendants on this motion - CAM seeks dismissal of Plaintiff's claims by arguing that (i) the MRI Kit should be considered a "component" of and/or an "accessory" to the Implant, and/or that (ii) the MRI Kit is actually a Class III device for which pre-market approval was obtained by virtue of its mere mention in the Supplemental PMA filed for the Implant. However, as explained below, the MRI Kit is neither a "component" nor "accessory" of the Implant under FDA regulations, and the PMA and Supplemental PMA obtained for the Implant do not extend to the MRI Kit and shield it from State law claims.

Finally, CAM argues the amended complaint should be dismissed because of alleged deficiencies in the allegations in the complaint under New York law. This argument too should be rejected, as Plaintiff has adequately pled claims for strict product liability, negligence, breach of warranty, and failure to warn against Defendants under New York law.

Accordingly, it is respectfully requested that CAM's motion to dismiss Plaintiff's amended complaint be denied in its entirety.

II. DISCUSSION

A. Standard of Review

A complaint should only be dismissed pursuant to Federal Rules of Civil Procedure 12(b)(6), if it does not contain enough factual allegations to state a claim for relief that are plausible

and rise above a mere speculative level. Bell Atlantic Corp. v. Twombley, 550 U.S. 544, 555 (2007). A claim is plausible on its face where, as here, the "plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Aschroft v. Iqbal, 556 U.S. 662 (2009). A complaint is considered plausible on its face, if it raises a reasonable expectation that discovery will reveal evidence to support the plaintiff's allegations. Towmbly, *supra*, at 556. "[A] well-pleaded complaint may proceed if it appears that a recovery is very remote and unlikely". Twombly, *supra*, at 556, *citing*, Scheuer v. Rhoades. 416 U.S. 232, 236 (1974). In deciding a motion to dismiss, the court is required to accept the material facts alleged in the complaint as true and draw all reasonable inferences in the plaintiff's favor. Aschroft, *supra*, at 662.

B. Plaintiff's Claims Are Not Preempted By MDA

i. The MDA Regulatory Framework

In 1976 Congress enacted the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FDCA"). *See*, 21 U.S.C. §360c et seq. The MDA was intended to impose a "**regime of detailed federal oversight**" in an area that had been previously regulated by state law. Riegel v. Medtronic, Inc., 552 U.S. 312, 316 (2008). Emphasis added.

Under the MDA, medical devices are categorized into three classes by the FDA, depending upon the risks they pose to the public and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

Class I devices generally pose the lowest risk to the patient and/or user and Class III devices pose the highest risk.

A medical device is categorized into Class III if it (i) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in

preventing impairment of human health, or (ii) presents a potential unreasonable risk of illness or injury". *See*, 21 U.S.C. §360 c (a)(1)(C).

Class II devices – such as the MRI Kit - are defined under the MDA as those "which cannot be classified as a Class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance…". *See*, 21 U.S.C.S. §360c (a)(1)(B).

Class II and III devices are subject to different approval and oversight by the FDA. Thus, the Implant and MRI Kit are subject to different approval processes and oversight.

Class III devices – such as the Implant - are subject to the FDA's most "rigorous regime" called the "premarket approval ("PMA") process". Riegel, *supra*, at 317-318. Most class III devices, however, go through the less rigorous review called §510(k) process if the new device is found to be "substantially equivalent" to another device exempt from PMA. Riegel, *supra*, at 317. "While 510(k) is 'focused on equivalence, not safety', internal citation omitted, premarket approval is focused on safety, not equivalence." Riegel, at 323.

Generally, Class II devices are regulated through "special controls" issued by the FDA. As such, a manufacturer of a Class II device must only submit a §510(k) application for FDA clearance before introducing a Class II device into interstate commerce, unless the device is exempted from this requirement. Pursuant to the Food and Drug Administration Act of 1997 ("FDAMA"), certain class I and II devices can be marketed without submitting a §510(k) application. Accordingly, in 1997, the FDA published a list of Class II devices that it determined did not require premarket notification to assure their safety and effectiveness before being

marketed[2]. Consistent with this determination, in the 1997 Convenience Kits Interim Regulatory Guidance, (*see*, Convenience Kits Interim Regulatory Guidance[3]) the FDA also identified certain Class II devices that are specifically exempt from §510(k) notification requirements. Importantly, MRI kits were specifically identified by the FDA as one of the exempted devices. Thus, since the promulgation of that list of exempted devices, manufacturers of MRI kits, including Defendants, have not been required to submit premarket notification applications to the FDA and FDA clearance has not been required to market MRI kits in the U.S. Thus, despite CAM's contention to the contrary, not only has the MRI Kit not obtained pre-market approval, such approval was not available for the MRI Kits.

ii. Express Preemption Under MDA

Pursuant to 21 USCS §360k(a), "no state may establish or continue in effect with respect to a device intended for human use any requirement which is different from or in addition to, any requirement applicable to the device under the Federal Food, Drug, and Cosmetic Act of 1938." Medtronic v. Lohr, 518 U.S. 470, 474 (1996). In order for a State law cause of action to be statutorily preempted, there must be (i) a Federal requirement imposed on the device; and (ii) the challenged State or local law must impose a requirement different from or in addition to the Federal requirements. Hence, the Court should begin its analysis with a determination of whether the FDA promulgated "specific" requirements applicable to the particular device.

It is undisputed that there can be no preemption under §360k (a) if, as here, the FDA has not imposed specific requirements upon the device in question. *See*, Riegel v. Medtronic, Inc., 552 U.S. 312, 321-322 (2008); Lohr, *supra*, at 493-494. *See*, also, 21 CFR § 808.1(d)(a) ("state

[2] See, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm?GMPPart=892#start
[3] Convenience Kits Interim Regulatory Guidance can be found at https://www.fda.gov/media/72720/download *See*, also Medical Devices; Exemptions from Premarket Notification; Class II Devices at https://www.govinfo.gov/content/pkg/FR-1998-01-21/pdf/98-1485.pdf

requirements are pre-empted **only when the Food and Drug Administration [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act**"). Emphasis added.

It is also well settled that pursuant to the standards set forth by the Supreme Court in Lohr and Riegel, MDA protection from State law claims does not apply unless the subject device has undergone the FDA's most rigorous review process (i.e. PMA). Indeed, even if the MRI Kit had been reviewed under a less stringent process (i.e. the §510(k) process) or, as here, had been exempt from the approval process (i.e. pursuant to the 1997 FDAMA exemption), State law causes of action regarding the device would still have been viable and would not have been preempted. Riegel, *supra*, at 322-323. (holding that PMA in contrast with the § 510(k) process, imposes "requirements" under MDA and is "device specific"). The holding in Riegel is in accord with the express legislative intent underpinning the MDA, which has been expressed as being intended to "provide for the safety and effectiveness of medical devices intended for human use." Lohr, *supra*, at 479; Riegel, 552 U.S.312. Said differently, because devices that are cleared for distribution through the §510(k) process and those devices, like the MRI Kit in the instant matter, which have been exempted from PMA and/or §510(k) process, are not required to provide the FDA with a reasonable assurance that the device is both safe and effective" and because the FDA does not promulgate device specific requirements during the §510(k) process or when a device is exempted from notification, State common law claims regarding their safety and effectiveness are not statutorily preempted.

In Riegel, the Supreme Court held that "[s]Ince the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirements applicable to the device' under

federal law, §360k(a)(1), we must determine whether the Federal Government has established requirements applicable to Medtronic's catheter." *Id*., at 321. The Riegel court further stated:

> "While §510(k) is 'focused on equivalence, not safety', *internal citation omitted*, premarket approval is focused on safety not equivalence. While devices that enter the market through §510(k) have 'never been formally reviewed under the MDA for safety or efficacy,' *ibid*, the FDA may grant premarket approval only after it determines that a device offers a reasonable assurance of safety and effectiveness, §360e(d). And while the FDA does not 'require' that a device allowed to enter the market as a substantial equivalent 'take any particular form of any particular reason,' *internal citation omitted*, the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness."

Id. at 323.

Here, as it will be demonstrated below, Plaintiff's claims are not expressly preempted, as the FDA did not impose specific requirements for the MRI Kit.

iii. Plaintiff's Claims

In her amended complaint, Plaintiff specifically alleged that she sustained severe injuries as a result of the MRI Kit's failure to function as designed, intended, represented and warranted by Defendants, she has made no claims implicating the Implant. Nevertheless, relying exclusively on the Supplemental PMA CAM filed for the Implant – which sought to permit the Implant to remain *in situ* during MRI, provided the MRI Kit was applied to the patient – Defendants urge the court to find that Plaintiff's claims against the MRI Kit are preempted. However, as show herein, the MRI Kit was not the subject of the Supplemental PMA, no law, rule or regulation permits the

extension of MDA protections to a separate Class II solely because it was mentioned in a filing PMA filing for a related product, and the FDA never promulgated or imposed "specific requirements" for the "MRI Kit". Accordingly, Plaintiff's claims are not preempted. Lohr, *supra*, at 474 (there is a presumption against preemption). Moreover, pursuant to FDAMA and the FDA's 1997 Convenience Kits Interim Regulatory Guidance[4], MRI kits produced by any manufacturer are designated "Class II devices" and are exempt from §510(k) notification requirements As such, they are not subject to MDA preemption. Riegel, at 322; also, *see*, Brackin v. Medtronic, Inc., 2017 WL 5957204 (W.D. Tenn. Sept 14, 2017) (where the court denied defendant's motion to dismiss in an action involving an insulin pump. The evidence did not establish that the product had received pre-market approval).

iv. The FDA Did Not Impose Any Specific Requirements Related to the Safety and Effectiveness of the MRI Kit

By conflating the two separate devices - the MRI Kit and Implant - CAM erroneously argues that the MRI Kit received PMA approval by virtue of its mention in the Supplemental PMA Defendants submitted for the Implant. However, Defendants' own submissions prove the MRI Kit was not the subject of the Supplemental PMA, as both Defendants and the FDA identified the Implant as the only device subject to the Supplemental PMA. *See*, Exhibit "A" to Defendants' moving papers in which only the Implant is identified as the device which was the subject of the PMA and Supplemental PMA.

CAM has submitted two PMA statements it obtained from the FDA. *See*, Exhibit "A" and "B" to CAM's moving papers. A review of those exhibits reveals that, contrary to what CAM claims, the FDA identified the specific device it reviewed and for which it issued approval:

[4] FDA last updated this last in July 2017, *see*, https://www.federalregister.gov/documents/2017/07/11/2017-14453/medical-devices-exemptions-from-premarket-notification-class-ii-devices

"Nucleus Cochlear Implant System" and the "Nucleus CI522 Cochlear Implant System", not the MRI Kit. *See*, below.

Device	NUCLEUS COCHLEAR IMPLANT SYSTEM
Generic Name	Implant, Cochlear
Applicant	Cochlear Americas 13059 East Peakview Avenue Centennial, CO 80111
PMA Number	P970051
Supplement Number	S137
Date Received	11/23/2015
Decision Date	07/08/2016

Device	NUCLEUS CI522 COCHLEAR IMPLANT SYSTEM
Generic Name	Implant, Cochlear
Applicant	Cochlear Americas 13059 East Peakview Avenue Centennial, CO 80111
PMA Number	P970051
Supplement Number	S126
Date Received	11/14/2014
Decision Date	06/15/2015

It is clear from CAM's own submissions that the MRI Kit was not identified as the device for which FDA review and approval was sought, only the Implant was the subject of the review and approval process, therefore, MDA preemption cannot be afforded to the MRI Kit. *See*, Kavalir v. Medtronic, Inc., 2008 WL 4087950 (N.D. Ill. Aug. 27, 2008) (denying preemption motion where "FDA internet pages" offered as evidence of PMA approval did not establish the "specific form" of approval that the "specific" product involved in the litigation had received); Kubicki v. Medtronic, Inc., 2013 WL 1739580 (D.D.C. 2013) (where the court denied defendants' motion based on preemption holding that "the Court need not, and on the incomplete factual record before it, shall not resolve the question at this early, pre-discovery stage of the litigation.")

CAM's submissions on this motion also fail to show that the FDA imposed any specific requirements upon the MRI Kit. The Supplemental PMA relied upon by CAM demonstrates that

Defendants only sought "a change in indication" for certain of its Implant devices, to allow recipients thereof to undergo MRI procedures at 1.5 Tesla with the Implants in place and at 3.0 Tesla with Implant's removal, they did not seek PMA for the MRI Kit, itself. In fact, at p. 7 of its Memorandum of Law in Support of Motion to Dismiss ("Def. Memo.") CAM tacitly acknowledged its Supplemental PMA application only involved the Implant and not the Kit when it said "[a]fter FDA's approval of a PMA, an applicant shall submit PMA supplement for review and approval by FDA before making a change and affecting the safety and effectiveness of **the device for which the applicant has an approved PMA**… changes for which an applicant shall submit a PMA supplement include, but are not limited to… (1) new indications for use of the device…; Riegel, at 319." Simply, CAM's Supplemental PMA submissions merely sought to change the indications for use of the Implant, and did not seek any approval for the MRI Kit, itself.

Next, CAM urges the court to adopt its mischaracterization of the MRI Kit as an "accessory" to the Implant, and to afford it immunity from State court claims on that basis. However, as we explain, (i) the MRI Kit is not an "accessory", (ii) Class II accessories are not entitled to Federal preemption, and (iii) the cases upon which CAM relies to make this wrongminded argument are inapposite; they address the treatment of "components", not "accessories".

Without addressing the important distinction between a "component" and an "accessory" under the FDA regulations, CAM asks the court to find that the MRI Kit is entitled to immunity from State claims as an "accessory", solely because other courts have found certain medical device "components" to be immune from State law claims. However, "accessories" are not "components" under the law, and the MRI Kit is not a "component" of the Implant; therefore, it is not entitled to the immunity often afforded "components" of Class III devices.

A "component" is defined as "any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." 21 CFR §820.3(c). Here, the MRI Kit was not ever intended to be part of the Implant - it is a wholly separate device – and, therefore it is not a "component" of the Implant. Indeed, Defendants do not expressly argue the MRI Kit is a "component" of the Implant, instead, they ignore the important distinction between accessories and components and rely on inapposite cases to seek extension of immunity to an "accessory".

Because it cannot credibly argue the MRI Kit is a component of the Implant, CAM argues the MRI Kit is an "accessory" of the Implant[5] and entitled to the immunity from State law claims often afforded components. The shortcomings of that argument are: (i) accessories are not entitled to the same immunity as components and (ii) the MRI Kit does not satisfy the criteria for being classified as an accessory of the Implant.

CAM argues the MRI Kit is an "accessory" because it "support[s], supplement[s], and/or augment[s] the performance" of the Implant, and, therefore, is entitled to immunity from State law claims. However, under the FDA's Medical Device Accessories Classification Guidance, a device is not considered an accessory of another device "simply because they may be used in conjunction" with that device. *See*, Medical Device Accessories-Describing Accessories and Classification Pathways Guidance for Industry and Food and Drug Administration Staff ("Accessory Guidance"), page 6[6]. To be an "accessory" a device must supplement, support or augment the related devices' performance.

[6] See, https://www.fda.gov/media/90647/download

Here, CAM describes the Implant as a device that "restore[s] a sense of hearing to those with severe to profound nerve deafness" (Def. Memo. at P. 1) by "electronically stimulating nerves inside the inner ear." (Def. Memo. at P. 1& 3). Implant "receives sound from the outside environment, process[es] that sound, and then send[s] small electric currents to an area near the auditory nerve." (Def. Memo. at P. 3). If we were to apply CAM's description of the effect the MRI Kit has on the Implant, it plainly does not "support, supplement and/or augment the performance" of the Implant. Nothing Defendants identify as a function of the MRI Kit (i.e. "stabiliz[ing] the magnet during certain MRI procedures" (Def. Memo. P.1)) supports, supplements and/or augments "restor[ation of] a sense of hearing". In fact, Defendants also admit that when the MRI Kit is applied to an Implant recipient's head, "the [Implant] recipient will no longer be able to hear" [1] and the Implant does not function. Accordingly, the MRI Kit cannot be considered an accessory to the Implant under FDA regulations.

Nevertheless, even if the kit was deemed an "accessory" to the Implant, that characterization, alone, would not result in preemption of the claims against the kit. There is no FDA rule or regulation, nor any case that extends the PMA obtained for one Class III device to an accessory that has not, itself, undergone review and approval under the FDA's PMA process.

Thus, even if the Court adopted CAM's view that the MRI Kit is an "accessory" to the Implant – which it is not under applicable FDA regulations - that acceptance would neither justify nor result in the extension of immunity from State claims to the MRI Kit. Such extension of immunity perhaps could have been accomplished had CAM filed a PMA application for the MRI Kit, but it never did that; it merely mentioned the MRI Kit in the Supplemental PMA it filed for the Implant.

As noted above, the MRI Kit was specifically identified by the FDA as a Class II device and was exempted from 510(k) approval by virtue of its inclusion on the list of exempted devices. Thus, the MRI Kit was never vetted by the FDA and the FDA never promulgated any specific rules applicable to the MRI Kit. Although CAM could have sought reclassification of the MRI Kit and could have filed a PMA request for the MRI Kit, it elected not to do so. Thus, the MRI Kit remains an unvetted Class II device for which immunity from State law claims is not available.

Thus, CAM is relegated to urging this Court to accept its unilateral reclassification of the MRI Kit as a Class III device, solely by virtue of its own characterization of the kit as an "accessory" to the Implant.

However, such reclassification - and extension of PMA - is not permitted by any FDA rule, regulation or by any case cited by CAM. Such reclassification could only have been accomplished pursuant to Section §513(f)(6)(C) of FD&C Act, which provides that, when an accessory has not already been classified, or when the manufacturer of an already classified accessory device seeks reclassification of the device, the manufacturer must submit an Accessory Request when submitting its FDA clearance application (i.e. PMA, supplemental PMA or §510(k) approval) for the parent device (here, the Implant), and specifically request classification/reclassification of an accessory. Importantly, "determining the risks of accessories according to their use with parent devices does not mean that all risks of a parent device are imputed to the accessory, the risk profile of an accessory can differ significantly from the parent device, warranting differences in regulatory classifications. In determining the classification of an accessory, FDA intends to evaluate the risks imposed by the accessory's impact on the parent device and any unique risks of the accessory independent of its parent device." *See*, Accessory Guidance, page 8.

Here, CAM failed to apply to the FDA to change the MRI Kit's classification to Class III or to have it classified as a Class III device accessory. Review of the PMA supplement for the Implants upon which CAM now relies, reveals Defendants never sought to have the MRI Kit approved as an accessory and the MRI Kit remains an unvetted Class II device.

Simply, Defendants' position that the MRI Kit should be afforded immunity from State law claims as an "accessory" to the Implant lacks any legal foundation. The FDA's prior classification of the kit as a stand-alone Class II device and CAM's prior decision not to submit a request to the FDA for re-classification of the MRI Kit as an accessory in accordance with the established FDA procedures enunciated at section §513(f)(6)(C) of the FD&C Act are fatal to CAM's argument on this motion. Indeed, even if CAM had sought reclassification of the MRI Kit as an accessory to a Class III device, the FDA would likely have denied that application because the MRI Kit was designed to be used with multiple "parent devices", and a device that has already been independently classified and which can be used with multiple "parent devices" cannot be reclassified. S*ee*, 21 CFR §807.20 (a)(6) (manufacturers of components and accessories are subject to device registration and reporting requirements).

Astonishingly, the single case relied upon by CAM where accessories rather than components are mentioned as having received PMA approval based on being introduced as an accessory to a Class III device, supports Plaintiff's argument that the **MRI Kit is not an accessory to the Implant**. *See*, Troutman v. Curtis, 143 P.3d 74, 78, 85 (Kan. Ct. App. 2006). Specifically, unlike the MRI Kit in the instant matter, the accessory in Troutman was referred to by FDA in the supplemental PMA as an accessory for which defendants sought and obtained PMA approval. A copy of the "PMA Supplement No. 19" in the Troutman case can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960043S019

As demonstrated above, Plaintiff's claims do not implicate §360k(a) of the MDA because the MRI Kit (i) is not a "component" of the Implant, (ii) has not been classified as an "accessory" to the Implant[7], (iii) did not, itself, receive premarket approval through the Supplemental PMA process, and (iv) is not otherwise subject to "device specific" federal requirements. Therefore, the court's preemption analysis should stop. The Court is not required to determine whether Plaintiff has sufficiently alleged specific violations of Federal requirements. *See*, Jacobs v. E.I. Dupont de Nemours & Company, 67 F. 3rd 1219 (6th Cir. 1995) (where the court found that because the FDA had not issued regulations specific to the device itself, defendant could not take advantage of the MDA's preemption provision); Lohr, *supra*, at 496 ("a state law will be pre-empted only to the extent that the FDA has promulgated a relevant federal 'requirement.'"); and 21 CFR §808.1(d)(a). Notably, more than half of the cases cited by CAM are distinguishable from the instant matter based on this ground. Those cases focus on the second and third steps the Court should take in considering an MDA preemption. However, as stated above, Court's analysis stops once it is demonstrated that "specific requirements" have not been imposed on the "particular device".

Furthermore, in the majority of cases cited by Defendants, there is no dispute between parties that the subject device is a Class III device and that it received PMA approval. In those cases, the only issues before the courts were whether plaintiffs had adequately pled violations of Federal requirements and whether the State requirements were parallel to the Federal requirements. *See*, Babayev v. Medtronic, Inc., 228 F. Supp. 3d 192 (E.D.N.Y 2017) (defendant's summary

[7] It should be noted that in a Physician Guide distributed by Defendants regarding the Implant, Defendants set forth the device's components as follows: the implanted components: a receiver/stimulator to receive and decode the electrical signals from the sound processor and electrode to deliver these signals; the external components: a sound processor, and associated accessories and cables. Nowhere in the list Defendants name the MRI Kit as a component or accessory of the Implant. A copy of the Physician Guide can be found at https://www.cochlear.com/8d89d122-dfd7-49ac-97eb-b63dd6c37b35/538751_3-01_EN_CI522_PG_CAM_web.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE-8d89d122-dfd7-49ac-97eb-b63dd6c37b35-ncSAJ.b

judgment motion was granted where there was not dispute that the subject device was a Class III device and that it had received MDA PMA, but because plaintiff failed to state parallel claims); Burkett v. Smith & Nephew Gmbh, 2014 WL 1315315 (E.D.N.Y. 2014) (motion to dismiss in an action involving hip replacement was granted where there was no dispute that the device was a Class III device and it received PMA as safe and effective. The only issue before the court was whether plaintiff sufficiently pleaded parallel claims); Cordova v. Smith & Nephew, Inc, 2014 WL 3749421 (E.D.N.Y. 2014); Crissi v. Johnson & Johnson Vision Care, Inc., 2016 WL 4502038 (E.D.N.Y. 2016); Franzese v. St. Jude Med. Inc., 2014 WL 2863087 (E.D.N.Y. 2014) (plaintiff's case was dismissed as plaintiff failed to identify specific federal regulations which defendant violated); Gale v. Smith & Nephew, Inc., 989 F. Supp. 2d 243 (S.D.N.Y. 2013); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271 (E.D.N.Y.2009) (the only issue before the court was whether plaintiff's state claims were parallel to federal requirements; neither party disputed that the subject device was a Class III device approved through PMA); Ilarraza v. Medtronic, Inc., 677 F. Supp. 2d 582 (E.D.N.Y. 2009) (where the district court noted that the parties agree that the device is a class III device that obtained FDA PMA, and that the only question before the court was whether plaintiff sufficiently stated parallel claims); In re Medtronic, Inc. v. Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010)(where plaintiff specifically conceded that the PMA supplement authorized the device to be used as it was used and disclaimed the need for further discovery; Tansey v. Cochlear, Ltd., 2014 W; 4829453 (E.D.N.Y 2014)(where plaintiff's design defect claims against the same Defendants were deemed preempted as the plaintiff who conceded that the Implant device was approved through PMA process but failed to allege specific PMA requirements regarding design defect. Plaintiff's manufacturing defects were deemed parallel and not dismissed); and Gross v. Stryker Corp., 858 F. Supp. 2d 466 (W.D. Pa. 2012) (where plaintiff's

submission of FDA's Summary of Safety and Effectiveness Data in opposition to the motion to dismiss demonstrated that specific requirements were imposed on the shell, the subject device, as a component of the Trident System, as such the court held that the subject device received PMA approval as a component of the device).

Here, in contrast to the cases cited by Defendants, the MRI Kit is a Class II device, not subject to PMA and specifically exempted from FDA clearance notification. Therefore, Defendants have failed to submit any legitimate support for their argument that the MRI Kit is entitled to immunity from State law claims.

The remainder of the cases cited by Defendants in support of their preemption argument are equally inapplicable to the instant case as those cases relate to the components of PMA-approved devices. As stated above, the only case cited by CAM, which mentions accessories rather than components, is also distinguishable from the instant matter. In Troutman, *supra*, the subject accessory was an accessory that had received FDA approval, an important factor missing in the instant matter; the FDA does not refer to the MRI Kit as an accessory to the Implant in the Supplemental PMA. Additionally, in Troutman, unlike in the instant matter, there was no dispute that the subject accessory was introduced as an accessory in a supplemental PMA. *See*, *Id.* at 634-635 ("the district court found the following facts to be uncontroverted. The district court's factual determinations have not been challenged on appeal and are summarized as follows: …9. With the submission of PMA Supplement No. 19, Perclose also introduced…the Clincher Knot Tying Device, a new accessory device that would automatically tie a sliding surgical knot in the suture).

Accordingly, Defendants have failed to establish that the MRI Kit entitled to immunity from State law claims as a component of or an accessory to the Implant device. The FDA did not

impose device specific requirements on the MRI Kit and, therefore, MDA preemption does not apply to Plaintiff's State causes of action.

C. Plaintiff's Allegations Satisfy Pleading Requirements

CAM next argues that Plaintiff's allegations fail to state a claim sufficient to meet the pleading standard established in Twombly, 550 US 544, 550 (2009) and Iqbal, 129 S. Ct. 1937, 1949 (2009). However, this argument too fails. As demonstrated below, Plaintiff's amended complaint contained sufficient facts to state strict product liability, negligence, breach of warranty and failure to warn causes of action. Indeed, Courts have repeatedly denied motions to dismiss product liability cases holing that in product liability cases, where, as here, almost all of the evidence is in the possession of defendant or other entities. *See*, Coene v. 3M Co., 2011 U.S. Dist. Lexis 89445 (W.D.NY. 2011), *citing*, Winslow v. W.L. Gore & Assoc., Inc., 2011 U.S. Dist. LEXIS 25520, 2011 WL 866184 (W.D. La. 2011) ("Additional information about the specific products at issue can be developed during discovery…This is a products liability case where almost all of the evidence is in the possession of defendant or other entities. Proof will necessarily be technical in nature and it is likely impossible for plaintiff to state more specific allegations regarding defects in manufacture and design without first having the benefit of discovery and of expert analysis, neither of which is required in order to file suit"); Coleman v. Boston Scientific Corp., 2011 U.S. Dist. LEXIS 42826, 2011 WL 1532477, 2-5 (E.D. Ca. Apr. 20, 2011); Hemme v. Airbus, S.A.S., 2010 U.S. Dist. LEXIS 31920, 2010 WL 1416468, 3 (N.D. Ill. Apr. 1, 2010) (rejecting defendant's argument, in products liability action involving defective electrical components in passenger jet, that the complaint's use of the "generic word 'wiring'" was insufficient, and that plaintiff had to "identify the particular product that was allegedly defective").

In Burgos v. Satiety, 2011 U.S. Dist. LEXIS 37138 (E.D.N.Y), this court, *citing* In re Medtronic, Inc., Spring Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200 (8th Cir. 2010), stated that "Plaintiff's pleading burden should be commensurate with the amount of information available to them. Other court have similarly observed that it would be an injustice to penalize a plaintiff for alleging through no fault of her own, what turned out to be insufficient facts about the manufacturing process of a device that caused injury". Court held that plaintiff has stated a cause of action for negligence stating that she "has diligently alleged as many facts as she can at this point".

Here, Plaintiff's complaint provided the grounds for entitlement to relief with more than labels and conclusions in accordance with the standard enunciated in Twombly, *supra*, at 550 (a complaint need not provide "detailed factual allegations" but must provide grounds for entitlement to relief).

i. Plaintiff's Negligence claims

To state a claim for negligence, a plaintiff must plausibly allege: (1) that Defendants owed him a duty recognized by law; (2) a breach of the duty; (3) a reasonably close causal connection between Defendants' conduct and the resulting injury; and (4) loss or damages resulting from the breach. McCarthy v. Olin Corp., 119 F. 3d 148, 156 (2d Cir. 1997).

Here, Plaintiff properly alleged all elements of negligence with sufficient facts. Plaintiff alleged that (1) Defendants owed her a duty of care not to design, manufacture or sell a negligently designed and/or manufactured MRI Kit (complaint ¶ 54); (2) Defendants breached that duty by distributing a product that they had actual and constructive notice of being negligently designed and/or manufactured; A product that did not protect users from Magnet dislodgment or dislocation (complaint ¶¶ 55 & 56); (3) the MRI Kit failed to function as designed, intended, represented and

warranted by Defendants (complaint ¶1); and (4) as a direct result of Defendants' negligent design and manufacture of the MRI Kit, Plaintiff sustained foreseeable injuries and damages (complaint ¶57).

CAM's claim that "Plaintiff failed to allege specific facts" fails as "it is well settled that a plaintiff may proceed on a negligence claim in the absence of evidence identifying a specific defect, provided that he or she can 'prove that the product did not perform as intended and exclude all other causes of the product's failure that are not attributable to defendants." Parillo v. Stryker Corp., 2015 U.S. Dist. LEXIS 191834, 6 (N.D.N.Y. 2015), *citing*, Riegel v. Medtronic, Inc., 451 F. 3d 104, 125 (2d Cir. 2006).

In the instant matter, Plaintiff alleges that the MRI Kit failed to function as designed, intended, represented and warranted by Defendants (complaint ¶1). Moreover, Plaintiff pleads that Defendants "ceased" selling or distributing the MRI Kit as a result of "observed inconsistencies in [the MRI Kit's] use by medical imaging professionals over time" and "post-market complaints and adverse event data, which also suggests inconsistencies with the patient experience and potential for pain and/or magnet dislodgment, sometimes requiring revision surgery, including possible device explantation and reimplantation" (complaint ¶35 &36). Drawing all reasonable inferences in favor of Plaintiff, as required in deciding a motion to dismiss, Plaintiff's allegations of negligence and strict product liability, for that matter, are sufficiently pled and are not mere legal conclusions, as CAM claims, but is supported by proof that Defendants withdrew the MRI Kit from market because of multiple magnet dislodgments, against which the kit was designed to protect. That recall, alone, provides ample circumstantial evidence that the MRI Kit was faulty. State Farm Fire & Cas. Co. v. Gen. Elec. Co., 2015 U.S. Dist. LEXIS 95828, 7 (N.D.N.Y. 2015) ("A plaintiff need not prove a specific defect but may provide circumstantial

evidence to support a finding that the product did not perform as intended and that other causes are excluded.") *See*, also, Williamson v. Stryker Corp., 2013 WL 3833081, 4, U.S. Dist. LEXIS 104445, 8 (S.D.N.Y. 2013). Accordingly, Plaintiff sustained her burden to state a plausible negligence claim against Defendants.

ii. Plaintiff's Strict Product Liability Claims

Under New York law, a defendant in a strict product liability case is liable to any person injured if there is a defect in a product sold by the defendant that was a substantial factor in bringing about the Plaintiff's injuries, provided that: (1) at the time of the occurrence, the product was being used in a manner that was intended, (2) the injured party would not have, by the exercise of reasonable care, discovered the defect and perceived its danger, and (3) that by the exercise of reasonable care, the person injured would not otherwise have averted the injury. Wheeler v. Sears Roebuck & Co., 37 A.D.3d 710, 831 N.Y.S.2d 427 (2nd Dept. 2007).

To establish a *prima facie* strict product liability case based on a manufacturing defect, a plaintiff must show that the product did not perform as intended and that it was defective when it left the manufacturer's control. Denny v. Ford Motor Co., 87 N.Y.2d 248, 662 N.E.2d 730, 639 N.Y.S.2d 250 (1995).

Here, Plaintiff claims that at the time of the design, manufacture, distribution, sale and/or use of the MRI Kit, the MRI Kit was not reasonably safe and fit for the purposes intended nor for reasonably foreseeable purposes and uses (complaint ¶44) and that it failed to meet to meet design-control and manufacturing requirements to ensure that it conformed to defined use, needs, intended purpose and uses (complaint ¶45).

CAM's argument that Plaintiff failed to state a cause of action for manufacturing defect because she failed to allege a specific "error in the manufacturing process" or "a defect compared

to other samples of that device" fails because, as stated above, it would be unduly burdensome to expect Plaintiff to have specific knowledge about Defendants' manufacturing process at this early stage of the case. *See*, Burgos, *supra*, at 12. Accordingly, Plaintiff sufficiently pled her manufacturing defect.

Plaintiff also pleaded sufficient facts to state her cause of action for design defect. To state a cause of action for design defect, Plaintiff was required to allege that the MRI Kit was "unreasonably dangerous for its intended use". Here, Plaintiff alleged that at the time of the design, manufacture, distribution, sale, and/or use of the MRI Kit, the MRI Kit was not reasonably safe and fit for the purposes intended, nor for reasonably foreseeable purposes and uses (complaint ¶43). CAM's argument that Plaintiff failed to plead how the MRI Kit was defectively designed or the existence of feasible alternative design at this early stage in the case without conducting discovery and without having retained an expert would be unfair as it "would require plaintiff to possess technical, scientific knowledge of the inner workings" of the MRI Kit and "directly contravenes the notice pleading requirement of Federal Rule of Civil Procedure 8, which still survives the Iqbal-Twombly analysis." Ohuche v. Merck & Co., 2011 U.S. Dist. LEXIS 73904, 9 (S.D.N.Y. 2011); Cowan v. Costco Wholesale Corp., 2017 U.S. Dist. LEXIS 1714, 6 (E.D.N.Y. 2017).

iii. Plaintiff's Failure to Warn Claims

Under New York law, a plaintiff alleging a failure to warn claim must demonstrate that "(1) manufacturer had a duty to warn, (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the

harm." State Farm Fire & Gas Co. v. Nutone, Inc., 426 F. App'x 8, 10 (2d Circ. 2011). These elements are satisfied, if plaintiff can show that the product did not contain adequate warnings.

Here, Plaintiff, in her complaint alleged that (i) Defendants had a duty to warn Plaintiff and Plaintiff's medical providers who were performing an MRI procedure on Plaintiff of the risks and dangers associated with the use of the MRI Kit in the manner it was intended to be used (complaint ¶66 & 67); (ii) Defendants failed to warn Plaintiff or the medical care providers of the risks and dangers associated with use of the MRI Kit in the manner it was intended to be used or in a reasonably foreseeable manner of use (complaint ¶68); and (iii) as a direct and proximate result of Defendants' failure to warn, Plaintiff was caused to sustain serious personal injury (complaint, ¶ 69).

Because Plaintiff adequately alleged her failure to warn claim based on Defendants' failure to communicate the dangers and hazards associated with the foreseeable and recommended use of the MRI Kit, Plaintiff satisfied the pleading requirements to state a cause of action for failure to warn under New York law. Saladino v. Stewart & Stevenson Servs., Inc., 704 F. Supp. 2d 237, 247 (E.D.N.Y. 2010).

iv. Plaintiff's Breach of Warranty Claims

A claim for breach of implied warranty is valid if plaintiff can show that the product "was being used for the purpose and in the manner intended" Derienzo v. Trek Bicycle Corp., 376 F. Supp. 2d 537 (S.D.N.Y. 2005), *citing*, Beneway v. Superwinch, Inc., 216 F. Supp. 2d 24, 30 (N.D.N.Y. 2002), and that plaintiff was caused injured. An "implied warranty is breached where [as here] the product in question is not fit for the ordinary purpose for which it is to be used." Denny v. Ford Motor Co., 87 N.Y.2d 248, 662, 662 N.E.2d 730, 736, 639 N.Y.S.2d 250 [1995].

In the instant matter, Plaintiff alleged that upon the sale of the MRI Kit, Defendants warranted, expressly and impliedly, that the MRI Kit was safe, merchantable and suitable and fit for the purpose for which it was intended (complaint ¶60). Plaintiff further alleged that Defendants warranted that Plaintiff could safely undergo an MRI procedure with her Implant magnet in place under skin provided the MRI Kit was used (complaint ¶61). Additionally, Plaintiff alleged that contrary to Defendants' warranties, the MRI Kit was unsafe, not merchantable, unsuitable and unfit for its intended purpose due to defects in its design, manufacture and/or construction, causing injury to Plaintiff (complaint ¶62). Accordingly, Plaintiff has alleged sufficient facts to state a cause of action for breach of implied warranty.

Finally, Plaintiff has alleged sufficient fact to state her breach of express warranty claims. Under New York law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods" or "any description of the goods and becomes "part of the basis of the bargain" creates an express warranty that the goods shall conform to the affirmation or promise." *See*, New York Uniform Commercial Code §2-313(1)(a). "To establish the breach of an express warranty, the plaintiff must show that there was an 'affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase' and that the warranty was relied upon to the plaintiff's detriment." Barrett v. Black & Decker (U.S.), Inc., 2008 U.S. Dist. LEXIS 108787, 31 (S.D.N.Y. 2008), citation omitted.

Here, as stated above, Plaintiff alleged that upon the sale of the MRI Kit, Defendants warranted expressly and impliedly, that said MRI Kit was safe, merchantable, suitable and fit for the purpose for which it was intended (complaint ¶60). Plaintiff further alleges that Defendants warranted that Plaintiff could safely undergo an MRI procedure with her Implant magnet in place under her skin provided the MRI Kit was used (complaint ¶61). Because "[a]ffirmations of fact

regarding the safety of a product are actionable on a claim for breach of express warranty", Plaintiff has adequately stated a cause of action for breach of express warranty and CAM's motion on this ground too should be denied. Williamson, *supra*, at 23-24.

D. If Deemed Necessary then Plaintiff Should Be Granted Leave to Amend the Complaint

If the Court finds Plaintiff's complaint is inadequate, which Plaintiff avers it should not, then Plaintiff requests leave to amend the complaint.

Rule 15 (a) of the Federal Rules of Civil Procedure provides that leave to amend a pleading "shall be freely given when justice so requires". Goldin v. Smith & Nephew, Inc., 2013 U.S. Dist. LEXIS 58811, 19-20 (S.D.N.Y. 2013).

III. CONCLUSION

For the foregoing reasons, CAM's motion to dismiss should be denied in its entirety; alternatively, Plaintiff respectfully requests leave to amend the complaint, if deemed necessary; and for such other and further relief as the Court deems just and proper.

Dated: New York, New York
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By: /s/Jonathan M. Goidel

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